

Appl. No. : 09/631,576
Filed : August 4, 2000

an optic;
a haptic;
a cleat on the lens; and
an eyelet on the haptic allowing said cleat to firmly attach to the haptic,
wherein said optic and said haptic are each configured to pass separately,
completely through a 2.5mm or less opening.

79. (New) An attachment for an IOL comprising:

an optic;
a haptic;
a cleat on the haptic; and
an eyelet on the lens allowing said cleat to firmly attach to the optic,
wherein said optic and said haptic are each configured to pass separately,
completely through a 2.5mm or less opening.

REMARKS

With this amendment, Claims 41, 46, 47, 73 and 76 are canceled, Claims 40, 48-51, 53-56, 66-69, 74 and 75 are amended, and Claims 77-79 have been added. Claims 40, 48-72, 74-75 and 77-79 are thus presented for further Examination.

The specific changes to the specification and the amended claims are shown on a separate set of pages attached hereto and entitled VERSION WITH MARKINGS TO SHOW CHANGES MADE, which follows the signature page of this Amendment. On this set of pages, the insertions are underlined while the deletions are stricken through.

Objections to the Specification

The Examiner has objected to the abstract of the disclosure. The title of the abstract has been corrected to match the title of the specification. The abstract has been amended such that it is a single paragraph. Accordingly, Applicants respectfully request withdrawal of the objections.

Double Patenting

The Examiner has provisionally rejected to Claims 40, 41, 46-52, 56-59, 61, 67, 75 and 76 as being unpatentable over Claims 1, 5-7, 16, 17, 19, 20, 22-24, 26, 27 and 36 of copending

Appl. No. : 09/631,576
Filed : August 4, 2000

Application No. 10/056,971 for obviousness-type double patenting. Applicants will address this rejection when the conflicting claims have been patented.

Rejections Under 35 U.S.C. § 112

The Examiner has rejected Claims 40, 41, and 46-76 under 35 U.S.C. § 112, second paragraph as failing to particularly point out and distinctly claim what is regarded as the invention.

Claim 40 has been amended to specify that the eyelet is located on the lens.

Claim 41 has been cancelled.

Claim 51 has been amended to recite that the haptic “further comprises at least one more cleat”.

Claims 54 and 55 have been amended to clarify the arrangement of the haptic. As described in the specification at page 11, lines 11-13, with reference to Figures 5A-E, “the haptic allows for insertion through a very small incision 500 by rotating the haptic as it is manipulated and moved into the eye 1.” The haptic insertion is described further at page 11, lines 13-25.

Claim 66 has been amended to remove “and the like”.

Claim 69 has been amended to remove “the eye tissue”. Claim 69 has also been amended to clarify that the hinge comprises a toe region, a foot region, and a lower modulus material extended toward the foot region.

Accordingly, Applicants respectfully request withdrawal of the rejections.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected Claims 40, 41, 46, 47, 49-52, 56, 67, 73 and 74 under 35 U.S.C. § 102(b) as anticipated by US Patent No. 4,268,921 to Kelman. The Examiner has rejected Claims 40, 46, 56, 67, 73, 75 and 76 under 35 U.S.C. § 102(b) as anticipated by US Patent No. 4,608,049 to Kelman. The Examiner has rejected Claims 40, 41 and 46-76 under 35 U.S.C. § 102(b) as anticipated by US Patent No. 5,201,763 to Brady et al. The Examiner has rejected Claims 40, 41, 46-52, 67 and 73 under 35 U.S.C. § 102(e) as anticipated by FR Patent No. 2 784 575 to Hanna.

Applicants have amended Claim 40 to recite that the two-part IOL comprises an optic, a substantially rigid haptic, a cleat on the haptic, and an eyelet on the lens allowing the cleat to

Appl. No. : 09/631,576
Filed : August 4, 2000

firmly attach to the optic, wherein the two-part IOL is configured to pass completely through a 2.5mm or less opening.

Kelman '921 and Kelman '049 do not teach or suggest an IOL comprising a cleat and an eyelet, as recited in Claim 40. Kelman indicates that "the first support member is held in the recess by detent means defined, by a threaded engagement of the support member in the recess." See Col. 2, lines 10-13. Figures 2 and 3 clearly show that the first support member is screwed into the lens body. Similarly, Kelman '049 discloses that the lens body 80 may be twisted relative to the loop 76 to force the hooks 81 into gripping engagement with the loop 76. See Col. 7, lines 58-60. Furthermore, Kelman '921 and '049 do not teach or suggest that the IOL can pass through a 2.5mm or less opening. In contrast, the IOL of the preferred embodiments include cleats that clip into the eyelets.

Brady is directed to an IOL having a haptic which includes a loop, and the material of the optic completely surrounds the attachment regions and fills the loops to strongly attach the fixation members to the optic at diametrically opposed locations. See Col. 6, lines 9-16. Brady also indicates that the IOL can be inserted into incisions of 3.2mm.

In contrast, the preferred embodiments of the present invention are directed to an IOL including a cleat on the haptic and an eyelet on the lens which engage to firmly attach the haptic to the optic, as recited in Claim 40. Furthermore, the IOL of the preferred embodiments is configured to pass through a 2.5mm or less opening.

Hanna is directed to an accommodating two-part IOL. Hanna discloses a peripheral part which is an elastically deformable annular piece shaped like a groove opening inwards with a rear wing in contact with the rear wall and a front wing in contact with the remaining peripheral part of the capsular bag front wall. Hanna also discloses that the front wing includes at least two tabs shaped like clasps radially projecting from the wing edge. Hanna discloses that the overall diameter of the IOL is at least 7mm.

It is physically improbable for the IOL as described in Hanna to be inserted through a 2.5mm or less opening, as required in Claim 40.

Accordingly, Applicant maintains Claim 40 is patentable over Kelman '921, Kelman '049, Brady and Hanna. As Claims 48-72 and 74-75 are dependent on independent Claim 40, Claims 48-72 and 74-75 are patentable for these reasons as well as for the limitations present in their independent parent claim.

Appl. No. : 09/631,576
Filed : August 4, 2000

New Claims

As indicated above, Applicant has added new Claims 77-79. Support for these claims is found in the specification. Applicant submits that these new claims also include a unique combination of features not taught or suggested by the prior art.

Claim 77 is directed to an IOL comprising an optic, a substantially rigid haptic, a cleat on the lens, and an eyelet allowing the cleat to firm attach to the haptic, wherein the IOL is configured to pass completely through a 2.5mm or less opening.

Claim 78 is directed to an IOL comprising an optic, a haptic, a cleat on the lens, and an eyelet allowing the cleat to attach to the optic, wherein the optic and haptic are configured to pass separately, completely through a 2.5mm opening.

Claim 79 is directed to an IOL comprising an optic, a haptic, a cleat on the haptic, and an eyelet allowing the cleat to firmly attach to the optic, wherein the optic and haptic are configured to pass separately, completely through a 2.5mm opening.

Applicants submit that the cited references do not teach or suggest these features, as discussed above with reference to the discussion under Rejections Under 35 U.S.C. § 102 with respect to Claim 40.

Thus, Applicant respectfully submits that this claim is in condition for allowance, and such action is respectfully requested.

CONCLUSION

The applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims pursuant to statutory sections 102, and/or 112, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of these amendments and remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, do not narrow the claims, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve

Appl. No. : 09/631,576
Filed : August 4, 2000

grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

If the Examiner has any questions which may be answered by telephone, he is invited to call the undersigned directly.

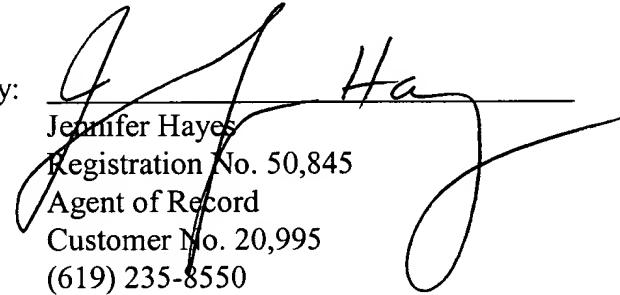
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 13, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The paragraph beginning at page 21, line 1, has been amended as follows.

TWO PART "L-V"-SHAPED PHAKIC IOL

Please replace the paragraph beginning at page 21, line 3, with the following rewritten paragraph.

A multi-part IOL which is insertable through an opening as small as about 1mm without deforming the haptic, is described. This IOL may be used in the anterior chamber of the eye for phakic or aphakic lenses. After insertion of the haptic into the eye, any type of lens may be attached, especially by use of cleats. ¶

The haptic is a high modulus skeletal frame, and may be assembled with lower modulus material and is attachable to cleats on the frame.

IN THE CLAIMS:

Claims 40, 48-51, 53-56, 66-69, 74 and 75 have been amended as follows:

40. (Amended) An attachment for a two-part IOL comprising:

an optic;

a substantially rigid haptic;

a cleat on one part of said two-part IOL the haptic; and

an eyelet on the lens allowing said cleat to firmly attach on said second part of
said two-part IOL to the optic,

wherein said two-part IOL is configured to pass completely through a 2.5mm or
less opening.

48. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said haptic comprises at least two cleats.

49. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said eyelet is on said lens.

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Appl. No. : 09/631,576
Filed : August 4, 2000

50. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said lens comprises at least two eyelets.

51. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said haptic further comprises at least one more attachment cleat.

53. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said haptic further comprises a hinge.

54. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said haptic comprises: ~~relatively more rigid elements~~

a first rigid element;

a second rigid element formed of a relatively higher modulus material than the first rigid element, wherein said first and second said relatively more rigid elements are separated from one another at a discontinuity; and

a relatively less rigid element formed of relatively lower modulus material bridging said discontinuity.

55. The attachment for a two-part IOL of Claim 54, wherein said bridging allows for the second element to be rotated rotationally fit into the anterior chamber.

56. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said haptic is composed of a higher modulus material selected from the group consisting of: polyimide, polyetheretherketone, polycarbonate, polymethylpentene, polymethylmethyl methacrylate, polypropylene, polyvinylidene fluoride, polysulfone, and polyether sulfone.

66. (Amended) The attachment for a two-part IOL of Claim 54, wherein said lower modulus material is selected from the group consisting of: NUSIL MED 6600, 6604, 6607, 6400, and 6820 and the like.

67. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein said optic is selected from the group consisting of a refractive lens, an interference lens, a toric lens, a multifocal lens, a positive lens, and a negative lens.

68. (Amended) The attachment for a two-part IOL of Claim 46 40, wherein a lower modulus material partially or completely covers said haptic.

69. (Amended) The attachment for a two-part IOL of Claim 46 53, wherein said hinge comprises a toe region, a foot region, and a lower modulus material is extended toward the foot region of said haptic to produce a softer contact point for the eye tissue.

Appl. No. : 09/631,576
Filed : August 4, 2000

74. (Amended) The attachment of Claim 56 40, wherein said two-part IOL is configured to pass completely through a 2.5mm or less opening without deformation to the haptic.

75. (Amended) The attachment for a two-part IOL of Claim 40, wherein ~~said two-part intraocular lens, comprises: a film haptic with a~~ the haptic is generally "L" shaped; and a separate optic.

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